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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,668

09/30/2005

Kazuo Imose

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RADER FISHMAN & GRAUER PLLC
LION BUILDING
1233 20TH STREET N.W., SUITE 501
WASHINGTON, DC 20036

EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT

PAPER NUMBER

4153

MAIL DATE

DELIVERY MODE

01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,668	Applicant(s) IMOSE, KAZUO	
	Examiner CHRISTIAN Y. JANG	Art Unit 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675) in view of Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome").

5. As to claim 1, Turcott discloses the invention substantially as claimed. Turcott teaches an examination apparatus, the apparatus having an output part for displaying or printing both of: (A) transition of respiratory airflow (Fig. 14, 410); and (B) transition of enhanced state of sympathetic nerve (Fig. 14, 418), of the subject patient during

sleeping (col 7, lines 25-27). Turcott further discloses that "an object of the invention is to monitor the status of a chronic disease in order to optimize medical therapy." (col 6, 43-45). However, Turcott does not disclose the use of the device in selecting patients for whom an oxygen therapy is effective.

Montserrat teaches the use of an oxygen therapy (commonly known as a continuous positive air pressure therapy) and its effectiveness for the purpose of treating patients with SAHS (sleep apnea/hypopnea syndrome).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to recognize the use of the device as taught by Turcott in selecting patients for whom oxygen therapy is effective in order to improve the symptoms and perceived health status of those suffering from a sleep respiratory disturbance.

6. As to claim 2, Turcott teaches the examination apparatus which comprises a unit for determining an electrocardiogram of the subject patient (col 7, lines 28-29), and an analysis unit for analyzing the enhanced state of sympathetic nerve based on the determined electrocardiogram wave form with a heart rate variability analytical procedure (col 7, lines 33-36).

7. As to claim 3, Turcott teaches the examination apparatus which comprises a sensor for detecting presence/absence or magnitude of respiratory airflow of the subject patient (Abstract), and an analysis unit (Fig. 1, 12) for analyzing synchronization of transition of the respiratory state in a Cheyne-Stokes respiratory symptom in which apnea and respiratory states are repeated with transition of abnormal enhancement of sympathetic nerve (col 7, lines 42-47).

8. Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675) and Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome") and further in view of Thomas et al. (US 2004/0144383).

9. As to claim 4, Turcott and Montserrat discloses the invention substantially as claimed. Turcott and Montserrat teach a therapeutic system which comprises an examination apparatus for use in selecting a patient for whom an oxygen therapy is effective among patients having a sleep respiratory disturbance, and/or use in ascertaining a therapeutic effect of the oxygen therapy wherein an output part for displaying or printing both of transition of respiratory airflow and transition of enhanced state of sympathetic nerve of the subject patient during sleeping is provided to the examination apparatus. However, Turcott and Montserrat does not disclose a supplying apparatus of an oxygen-enriched gas for respiration for the purpose of carrying out the oxygen therapy.

Thomas teaches a gas system for supplying pressurized gas (Abstract) for the purpose of providing a gas mix effective for stabilizing breathing of target patients or users. In addition, Thomas teaches that the control processor of the device may be responsive to patient state information ([0030], lines 1-5)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Turcott and Montserrat with the continuous positive air pressure therapy system as taught by Thomas in order to enable treatment of the respiratory disturbance.

10. As to claim 5, Thomas teaches the therapeutic system wherein the supplying apparatus of an oxygen-enriched gas for respiration is constituted to allow flow rate of the oxygen-enriched gas for respiration to be regulatable within a predetermined range so that the flow rate becomes the amount prescribed on the basis of the result displayed or printed by the output part of the examination apparatus ([0014], lines 1-11).

11. As to claims 6-9, Turcott, Montserrat, and Thomas teach a method of selecting a patient containing all the limitations found in the claims. The use of the system in claims 1-5 comprises the method claimed, and is rejected accordingly for the same reasoning.

12. As to claims 10-13, Turcott, Montserrat, and Thomas disclose the invention substantially as claimed.

They do not teach selecting a patient who exhibits the results that an arterial oxygen saturation is not higher than a predetermined threshold value. However, Turcott's disclosure includes an optical sensor to determine arterial blood oxygen saturation. Oxygen toxicity, severe hyperoxia caused by breathing oxygen at elevated partial pressures, is a well known and established medical concept. Thus, it is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Turcott, Montserrat, and Thomas to exclude patients who exhibit oxygen levels above an established saturation point so that the therapy they receive do not result in hyperoxia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Thurs. (7AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CJ
/C. Y. J./
Examiner, Art Unit 4153
1/17/08

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4153